REMARKS

This paper is responsive to the Office Action mailed June 14, 2010. In the Office Action, the Examiner issued a non-final rejection of claims 1, 2, 4, 6-8, 10, and 21-33. Claims 3, 5, 9, and 11-20 were previously canceled.

35 USC 103(a) rejections:

Claims 1, 2, 4, 6-8, 10, 21-30 and 33 were rejected under 35 USC 103(a) as being unpatentable over Hoste (US 6,508,806)("Hoste") in view of van Muiden (EP 0662385)("van Muiden"). Claims 31 and 32 were rejected under 35 USC 103(a) as being unpatentable over Hoste in view of van Muiden, as applied to claims 21 and 27, and further in view of Garabedian et al. (US 6,171,295)("Garabedian").

It is generally desirable to maintain the wall thickness of an introducer sheath as thin as possible. In this manner, the largest possible device can be passed into a body vessel through a sheath that has been inserted through the smallest possible entry hole. Prior art introducer sheaths are typically provided with either a coil or a braid reinforcement. A braid is typically utilized when it is desirable to enhance the torqueability of the sheath, whereas a coil is typically utilized to enhance the kink resistance of the sheath. (Application, paragraph [0003]).

In theory, combining these two reinforcements in a single sheath would enhance both torqueability and kink resistance. However, utilizing both reinforcements in an intermediate layer (rather than utilizing only one of them as is common in the art) requires a greater wall thickness than would be required if only a single reinforcement was utilized. Although the wall thickness of the sheath may be increased in order to accommodate two reinforcements, increasing the wall thickness of a sheath is generally undesirable, as it may preclude use of the sheath in instances when the desire for a small entry hole is paramount. In addition to the increased wall thickness that results when two reinforcements are used, the combination of the two reinforcements in a single sheath may cause the wire or monofilament layers of the respective coil and braid to interfere with each other. Interference of this type is even more likely when the reinforcements are positioned in close proximity to each other

in an attempt to minimize the increase in wall thickness of the sheath to the extent possible. When this occurs, the resulting device may have neither good torqueability nor good kink resistance. (paragraph [0005]).

Claims 1, 2, 4, 6-8, 10 and 33:

Claim 1 of the present application addresses the problems of providing a sheath having both a coil (for enhanced resistance to kinking) and a braid reinforcement (for enhanced torqueability), and yet maintaining the wall of the sheath as thin as possible. Neither of the cited references teaches or suggests such a combination in a thin-walled catheter.

Claim 1 is directed to a method of manufacturing an introducer sheath. A coil is positioned over a mandrel. A first polymeric sleeve is positioned over the coil and the mandrel, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along an outer surface of the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch extending in a generally opposite direction from a pitch of the first striped extrusion. A heat shrink tube is positioned over an assembly comprising the mandrel, coil, and first and second sleeves. The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, such that the first and second polymeric sleeves melt together to form a tubular polymeric sheath body enveloping the coil, wherein the second striped extrusion is superposed over the first striped extrusion in the sheath body to define a generally braid-like configuration therein disposed radially outwardly from the coil.

According to the Examiner, Hoste teaches a method of making an introducer sheath including positioning a coil over a mandrel, positioning a second reinforcing member over the coil wherein the second reinforcing member has a braid configuration, and heating the assembly in a heat shrink tube. The Examiner has acknowledged that Hoste does not teach positioning two sleeves with striped extrusions on the coil. Van Muiden was cited for allegedly teaching a method

wherein a second sleeve with a striped helical pattern was positioned over a first sleeve to define a braid-like configuration.

Hoste teaches a catheter construction for use, e.g., in guiding or angiography catheters for angioplasty procedures. As noted by Hoste, clinical requirements from utilization of guiding catheters to advance electrophysiology catheters have resulted in an increase in the transverse dimensions of the inner lumen of such catheters in order to accommodate a greater variety of intracorporeal devices. This increase in the transverse dimensions of the inner lumen has been accompanied with a decrease in the outer transverse dimensions of the guiding catheter, in order to present a lower profile and facilitate advancement within the patient's body lumens and openings. The catheter construction of Hoste is intended to allow for continued thinning of the catheter wall while facilitating the formation of the shape of the distal end of the catheter. Col. 2, lines 21-32.

Notwithstanding Hoste's recognition of the desirability of "continued thinning of the catheter wall", his catheter construction (Fig. 3) includes the combination of a radially inner braid 17 ("oblique wound layer"), a radially outer coil 18 ("circumferential wound layer"), and an outer jacket 19. As stated by Hoste, the order of the reinforcing layers can be reversed if desired. Hoste's arrangement of discrete braid and coil layers 17, 18, and outer jacket 19 is best shown in Figs. 2 and 3. In this regard, the Hoste structure is similar to that described as Background in the present application. See, e.g., paragraphs [0005]-[0006] (version as filed). Thus, notwithstanding the desire to achieve a thin-walled construction, Hoste's arrangement did not deviate in pertinent part from the conventional alignment of the braid and coil as described in the Background.

According to the Examiner, van Muiden teaches that it is known to form reinforcing members by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a braid-like configuration. Col. 4, lines 25-44). An extrusion profile 30 is made up of two coaxial layers 31, 32, each having a number of extruded helically shaped bands of material. The bands of material 33 in

the outermost layer 31 are running in the opposite direction to the helically shaped bands of material 34 in the innermost layer 32. Upon extrusion, a bond can be formed between the two layers with the helically shaped layers of material formed inside.

However, as shown in Fig. 4 of van Muiden, the sheath maintains the integrity of the separate layers 31, 32. Thus, even though van Muiden recognizes the trend toward ever thinner catheters (Col. 1, line 31), he maintains two separate layers in order to provide his substitute for a conventional braided reinforcement. In fact, according to van Muiden, the combination of the two layers is necessary to provide the effect of only a single reinforcing element, in this case a braid (Col. 1, lines 15-17). No teaching or suggestion of a heat shrink step to radially compress the layers is provided. In addition, no teaching or suggestion is provided of a manner by which the structure of van Muiden could be combined with a coiled reinforcement, nor is it apparent how this could be done and, at the same time, maintain a thin-walled catheter. In fact, a sheath resulting from the claimed combination may not even be useable in some instances in which a smaller diameter sheath is required, much in the same manner as the prior art sheath having both a braid and a coil as referenced in the Background of the present application.

Unlike either of the cited references, the method of claim 1 addresses the problem of providing both kink resistance and torqueability in a thin-walled sheath by positioning dual polymeric sleeves over a mandrel in the manner described above, and then heating the sleeves as described. A separate coil reinforcement is provided, and the sleeves are melted together in a manner such that the sheath outer layer includes the superposed striped extrusions that define the braided reinforcement. Thus, separate defined sleeves for providing these features are not required. Similarly, a discrete outer layer is also not required. Neither reference teaches or suggests such an elegant arrangement as claimed herein.

As the Examiner noted, Hoste does not teach positioning two sleeves with helical stripes on a coil. Although Hoste recognized the desirability of providing a thin catheter wall, he designed his catheter in a manner to maintain two separate reinforcement layers 17, 18, covered by yet another layer, namely outer jacket 19.

Although the teaching of van Muiden was in the available art, Hoste did not see fit to combine such teachings with his design as disclosed, in order to accomplish his stated desire of achieving a thinner catheter wall. Similarly, van Muiden attempts to mimic a braid reinforcement with his structure comprising striped layers 31, 32. He does not teach or suggest melting the two outer layers (31, 32) (e.g., no heat shrink step) to obtain the low profile that he refers to as a desirable feature. Rather, by maintaining two outer layers, he teaches away from the desirability of providing a sheath having as small a wall thickness as possible, and does not indicate how his desire for a thin-walled sheath can be achieved if a coil and outer jacket are combined with his structure.

Applicant respectfully submits that the test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, what the combined teachings of the references would have suggested to those of ordinary skill in the art. Further, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In making a prima facie determination of obviousness, the Examiner should identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Applicant respectfully submits that a prima facie case of obviousness of claim 1 in view of the cited combination has not been set forth by the Examiner. Each of the references recognizes the desirability of providing a thin-walled sheath, yet the references fail to teach or suggest the elegant solution to the problem arrived at by the present claims. In fact, Hoste maintains a structure having discrete layers 17, 18, 19 as described. van Muiden's combination of the dual outer sleeves does not advance the desire of maintaining a low wall thickness in the elegant manner as claimed herein. Applicant submits that no articulated reasoning with rational underpinning has been provided to support the obviousness finding, as required, and that it is only

after the benefit of Applicant's disclosure is gained that the features of the invention may appear to be obvious. Neither of the citations, either individually or in combination, teaches or suggests the manner of incorporating a braid-like configuration into a thin-walled sheath as claimed, nor do they teach or suggest a structure that is capable of enhanced bonding between the inner and outer layers as described.

In the present rejections, each of the cited references recognizes the desirability of providing a thin-walled catheter. Notwithstanding this desirability, neither reference was able to arrive at a solution to this problem in the manner of the claimed method. Applicant submits that absent the application of hindsight utilizing the present claims as a blueprint, the solution is not derivable from the cited combination.

Claims 2, 4, 6-8, 10, and 33 depend from claim 1, directly or indirectly, and therefore include all of its limitations. Accordingly, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 1 is not obvious.

Claims 21-30:

Claim 21 is directed to a method of manufacturing an introducer sheath. An inner liner is positioned over a mandrel, and a coil is positioned over the mandrel. A first polymeric sleeve is positioned over the coil, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch generally opposite a pitch of the first striped extrusion. The second sleeve is aligned over the first sleeve such that upon a melting of the sleeves the second striped extrusion is superposed over the first striped extrusion, and a generally braid-like configuration is defined thereby. A heat shrink material is positioned over an assembly comprising the mandrel, inner liner, coil, and first and second sleeves. The

assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, wherein the first and second sleeves melt together to form an outer tubular layer and to define the generally braid-like configuration therein, and the heat shrink material causes the outer tubular layer to bond to the inner liner through the coil turns.

The steps of this claim are generally illustrated in the figures, such as the sequence of Fig. 6. At a minimum, the cited art does not teach or suggest the feature of combining first and second sleeves having respective striped extrusions as described over an inner liner and a coil, and melting the first and second sleeves in a heat shrink enclosure to form an outer tube (e.g., paragraphs [0029] and [0032]). In this manner, a sheath is obtained having the desirable features of 1) a thin wall; 2) enhanced kink resistance provided by the radially inner coil; and 3) enhanced torqueability provided by the braid-like arrangement of the first and second striped extrusions. Such a sheath is clearly not derivable from the prior art methods referenced by the Examiner, either individually or in combination.

The Examiner has acknowledged that Hoste does not explicitly teach the "positioning" steps of the claimed method that involve the arrangement of the two polymeric sleeves. Accordingly, Hoste also cannot teach or suggest the "heating" step that causes the first and second "positioned" sleeves to melt together to form the *outer* tubular layer. Van Muiden was said to teach a two layer polymer sleeve for a catheter including striped helical patterns for defining a braid-like configuration. Van Muiden, however, does not teach or suggest the manner of achieving the braid-like action based upon the melting together of dual layers, each having a generally helical extrusion, wherein the extrusions in one layer have an oppositely-directed pitch from the extrusions in the other layer. Similarly, van Muiden does not teach or suggest the use of dual (coil + braid) reinforcements, nor is there any suggestion how such combination can be achieved while maintaining a thin-walled catheter. Applicant respectfully submits that the combined disclosures of the cited references fall well short of teaching or suggesting the claimed method. There is no basis, other than hindsight, for combining these two references in a manner to construct a dual reinforcement sheath, since no such teaching or suggestion is provided in either

reference. Further, even when such impermissible hindsight is utilized, the combination falls short of the features of the claimed method.

Claims 22-30 depend from claim 21, directly or indirectly, and therefore include all of its limitations. Accordingly, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 21 is not obvious.

Claims 31-32:

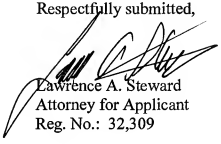
Claim 31 depends from claim 27. This claim includes the limitation that at least one of the polymeric sleeves includes a radiopaque sleeve distal of the distal segment. Claim 32, dependent from claim 32, includes the further limitation that the radiopaque sleeve has a lower durometer than the distal segment.

Each of claims 31 and 32 depends, indirectly, from claim 21, and therefore, includes all of its limitations. Garabedian does not teach or suggest the features described above that are lacking when the Hoste/van Muiden combination is made. Accordingly, claims 31 and 32 are also not obvious for at least the same reasons that claim 21 is not obvious.

Conclusion:

Based upon the foregoing, Applicant respectfully submits that the grounds for rejection of the claims have been overcome, and that all claims 1-2, 4, 6-8, 10, and 21-33 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a timely notice of allowance. If the Examiner believes that further prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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